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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/669,543 | 09/23/2003 | **Michael P. Wallace** | 03-398 (US01) | 4647 |

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| EXAMINER | |
|---|---|
| YABUT, DIANE D | |
| **ART UNIT** | **PAPER NUMBER** |
| 3734 | |

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| 07/27/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/669,543 | WALLACE, MICHAEL P. | |
| | Examiner | Art Unit | |
| | DIANE YABUT | 3734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04/02/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,10,11,13-16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,11,13-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/2/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This action is in response to applicant's amendment received on 04/02/2009.

### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on 04/02/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Engelson** (U.S. Patent No. **5,749,894**) and **Ragheb et al.** (U.S. Patent No. **5,824,049**).

Claims 1-2 and 6: Lee discloses detaching a vaso-occlusive device ("coil") **3** from a delivery catheter **1** to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body including an aneurysm, and delivering energy from an energy emitting element ("induction coil") **13** located outside the body to thereby heat the vaso-occlusive device at the target site (Figures 1-2 and col. 2, lines 50-65).

Lee does not expressly disclose the vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating, wherein the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated or when the polymeric material at least partially melts or softens, wherein the energy-emitting element is a radio frequency device. Lee also does not expressly disclose melting and fusing together portions of the coil for stability in a three-dimensional shape.

Engelson teaches a vaso-occlusive device or coil comprising a polymeric material coating which is heated by an energy-emitting element, or a radio frequency device (see abstract; col.1, lines 4-17, col. 4, lines 11 to col. 5, line 64, and col. 6, lines 1-10). The delivered heating energy causes a coating on the vaso-occlusive device to at least partially melt or soften (col. 9, lines 20-37). Engelson also teaches melting and fusing together portions thereof to stabilize the coil in the three-dimensional shape. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a polymeric coating on the vaso-occlusive device heated by radio frequency energy, as taught by Engelson, to Lee since it was well known in the art to use a polymeric material for endovascular therapy that acts as the glue or a means for making the vaso-occlusive device self-adherent without causing substantial harm to the tissue or the blood (col. 4, lines 26-29), and that bioactive agents may be advantageously released by heating the coil.

In addition, it is well known in the art to provide bioactive materials on a device in order to provide advantageous effects on the body, such as promoting healing and

preventing infection, and therefore it would be obvious to one of ordinary skill in the art to modify the invention of Lee with bioactive agents. Furthermore, Ragheb et al. teach a device **12** with a therapeutic bioactive agent coating **18** being substantially covered by a polymeric coating **20**. It would have been obvious to one of ordinary skill in the art at the time of invention to cover a bioactive agent coating with a polymeric material coating, as taught by Ragheb et al., to Lee to protect the bioactive agent coating from being released until desired, and therefore more effectively delivering the therapeutic agents to the surgical site after being navigated through the vasculature (col. 3, lines 15-19).

4. Claims 3-4, 10-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Engelson** (U.S. Patent No. **5,749,894**) and **Ragheb et al.** (U.S. Patent No. **5,824,049**), as applied to claim 1 above, and further in view of **Yamasaki** (U.S. Pub. No. **2004/0215124**).

Claims 3, 10-11, 13: Lee, Engelson, and Ragheb et al. disclose the claimed invention, including sufficiently heating the device to cause coagulation of blood at the target site (col. 2, lines 60-65), except for the energy-emitting element comprising a magnetic resonance device, positioning the body in a magnetic resonance imaging ("MRI") device, and activating the MRI device to apply a variable magnetic field to the body.

Yamasaki teaches a method and apparatus for aneurismal treatment using a heating source or energy-emitting element comprising a magnetic resonance device

(page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the energy-emitting element outside the body in Lee by providing a magnetic resonance device, as taught by Yamasaki, since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Yamasaki also teaches positioning the body in a magnetic resonance imaging ("MRI") device and activating the MRI device to apply a variable magnetic field to the body, which would thereby heat a highly resistive element in the vaso-occlusive device (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a magnetic resonance device as a source, as taught by Yamasaki, to Lee, Engelson, and Ragheb et al. since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Claim 4: Lee, Engelson, and Ragheb et al. disclose the claimed invention except for the vaso-occlusive device comprising a ferrous material in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device.

Yamasaki teaches a ferrous material ("magnetically responsive particles $Fe_3O_4$") in sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device (page 1, paragraph 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a vaso-

occlusion device comprising a ferrous material that responds to applied energy so that the device remains cohesive (page 1, paragraph 5) and therefore to properly treat the target site.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Engelson** (U.S. Patent No. **5,749,894**) and **Ragheb et al.** (U.S. Patent No. **5,824,049**), as applied to claims 1 and 19 above, and further in view of **Maitland** (U.S. Patent No. **6,740,094**).

Claim 5: Lee, Engelson, and Ragheb et al. disclose the claimed invention except for the energy-emitting element comprising an ultrasound device acoustically coupled to an exterior of the body.

Maitland teaches a source comprising an ultrasound device acoustically coupled to an exterior of a body, which allows for both local and remote heating (col. 6, lines 26-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the energy-emitting element outside the body in Lee by providing an ultrasound device source, as taught by Maitland, in order to allow for both local or remote heating and since it was known in the art that acoustic/ultrasound waves effectively heat materials that are commonly used in vaso-occlusive devices that absorb ultrasonic energy.

6. Claims 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lee** (U.S. Patent No. **6,397,107**) in view of **Engelson** (U.S. Patent No. **5,749,894**), **Ragheb et al.** (U.S. Patent No. **5,824,049**), and **Ken** (U.S. Patent No. **5,853,418**).

Claims 14-16 and 18: Lee, Engelson, and Ragheb et al. disclose the claimed invention, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device in an aneurysm and applying magnetic field energy to the device from an energy-emitting element located outside of the body, and a highly conductive metallic coil **3** having a lumen that interacts with a magnetic field to form an eddy current and melting and fusing together portions thereof to stabilize the coil in the three-dimensional shape (see paragraph 2 above) and sufficiently heating the device to cause coagulation of blood at the target site (Lee, col. 2, lines 60-65), but do not disclose a highly resistive element comprising a ferrous material at least partially disposed in the lumen which is heated by way of convective heat transfer from the highly resistive element.

Ken teaches a resistive element **214** containing ferrous material in the lumen of a highly conductive coil **202** which may be heated by way of convective heat transfer from the highly resistive element (Figure 1C; col. 4, line 61 to col. 5, line 10). Although Ken does not expressly disclose the resistive element being of a sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a resistive element within the lumen of the coil in Lee in order for the material to respond to applied energy so that the device remains cohesive

to properly treat the target site and also since it was well known to provide a concentration of magnetically responsive material high enough so that the device may be heated more rapidly. It is also noted that the "modest amounts of iron" disclosed in Ken does not necessarily render the device to have an insufficient concentration of iron to cause heating in response to magnetic energy.

***Response to Arguments***

7. Applicant's arguments filed 04/02/2009 have been fully considered but they are not persuasive.

8. Applicant generally argues that combining Lee, Engelson and Ragheb would not have prompted a person of ordinary skill in the art at the time of invention since the bioactive agent taught in Ragheb would have been released prior to heating since it has a porous polymeric coating, rather than being released or activated when the vaso-occlusive device is heated. However, the teaching cited by the examiner refers to the device of Raghreb advantageously using releasable bioactive materials, such as antimicrobials or antibiotics (col. 3, line 51), that are protected by a polymer coating to avoid degradation of the bioactive materials (col. 3, lines 50-54). In addition, Engelson teaches using a polymeric coating over a vaso-occlusive coil, since it was well known in the art that polymeric material for endovascular therapy acts as the glue or a means for making the vaso-occlusive device self-adherent without causing substantial harm to the tissue or the blood (col. 4, lines 26-29, Engelson). Modifying Lee's heated embolic coil with a polymeric coating, which may protect an advantageous bioactive agent from

degradation would have occurred to one of ordinary skill in the art since the benefits of self-adherence and resisting infection after delivering and heating the coil would promote proper embolization. It is also noted that the claims do not recite that the bioactive agent is only released or activated until after the vaso-occlusive device is heated, but rather that heating the vaso-occlusive device melts the polymeric material and releases the bioactive agent specifically at the treatment site.

9. In addition, applicant argues that there is no apparent reason for modifying the combined invention of Lee, Engelson, and Ragheb with Yamasaki. As maintained above, modifying the heat source for heating the coil of Lee would have been obvious to one of ordinary skill in the art since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy. In addition, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a vaso-occlusion device comprising a ferrous material that responds to applied energy so that the device remains cohesive (page 1, paragraph 5) and therefore to properly treat the target site, which is an advantage in an embolization that would be recognized by one of ordinary skill in the art.

10. Applicant then argues that Maitland does not remedy the deficiencies of Lee, Engelson, and Raghreb. As maintained above, Maitland teaches a source comprising an ultrasound device acoustically coupled to an exterior of a body, which allows for both local and remote heating (col. 6, lines 26-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the energy-emitting element

outside the body in Lee by providing an ultrasound device source, as taught by Maitland, in order to allow for both local or remote heating and since it was known in the art that acoustic/ultrasound waves effectively heat materials that are commonly used in vaso-occlusive devices that absorb ultrasonic energy.

11. Lastly, applicant argues that Ken does not provide evidence that modest amounts of iron would be highly conductive, as required by the claims. As mentioned, above, the examiner admits that although Ken does not expressly disclose the resistive element being of a sufficient concentration to cause heating of the device in response to energy delivered by the magnetic resonance device, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a resistive element within the lumen of the coil in Lee in order for the material to respond to applied energy so that the device remains cohesive to properly treat the target site and also since it was well known to provide a concentration of magnetically responsive material high enough so that the device may be heated more rapidly. It is also noted that the "modest amounts of iron" disclosed in Ken does not necessarily mean that the device possesses insufficient concentration of iron to cause heating in response to magnetic energy.

## ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734